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09/30/03

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EL 976544571 US

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
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☐ *Additional inventors are being named on the _____ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

METHOD AND APPARATUS FOR ELECTRIC CONTACTS ON A SAMPLE CARTRIDGE

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 9
☑ Drawing(s) *Number of Sheets* 5
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) Return postcard APPLICATION COVERSHEET

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Hao Y. Tung

Date 09/30/2003

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REGISTRATION NO. *(if appropriate)* 43,209

Docket Number: 38187-2696

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Attorney Docket No.: 38187-2696

PROVISIONAL PATENT APPLICATION

METHOD AND APPARATUS FOR ELECTRIC CONTACTS ON A SAMPLE CARTRIDGE

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Attorney Docket No.: 38187-2696

METHOD AND APPARATUS FOR ELECTRIC CONTACTS ON A SAMPLE CARTRIDGE

BACKGROUND OF THE INVENTION

Lancing devices are known in the medical health-care products industry for piercing the skin to produce blood for analysis. Typically, a drop of blood for this type of analysis is obtained by making a small incision in the fingertip, creating a small wound, which generates a small blood droplet on the surface of the skin.

Early methods of lancing included piercing or slicing the skin with a needle or razor. Current methods utilize lancing devices that contain a multitude of spring, cam and mass actuators to drive the lancet. These include cantilever springs, diaphragms, coil springs, as well as gravity plumbs used to drive the lancet. The device may be held against the skin and mechanically triggered to ballistically launch the lancet. Unfortunately, the pain associated with each lancing event using known technology discourages patients from testing. In addition to vibratory stimulation of the skin as the driver impacts the end of a launcher stop, known spring based devices have the possibility of firing lancets that harmonically oscillate against the patient tissue, causing multiple strikes due to recoil. This recoil and multiple strikes of the lancet is one major impediment to patient compliance with a structured glucose monitoring regime.

Success rate generally encompasses the probability of producing a blood sample with one lancing action, which is sufficient in volume to perform the desired analytical test. The blood may appear spontaneously at the surface of the skin, or may be "milked" from the wound. Milking generally involves pressing the side of the digit, or in proximity of the wound to express the blood to the surface. In traditional methods, the blood droplet produced by the lancing action must reach the surface of the skin to be viable for testing.

When using existing methods, blood often flows from the cut blood vessels but is then trapped below the surface of the skin, forming a hematoma. In other instances, a wound is created, but no blood flows from the wound. In either case, the lancing process cannot be combined with the sample acquisition and testing step. Spontaneous blood droplet generation with current mechanical launching system varies between launcher

types but on average it is about 50% of lancet strikes, which would be spontaneous. Otherwise milking is required to yield blood. Mechanical launchers are unlikely to provide the means for integrated sample acquisition and testing if one out of every two strikes does not yield a spontaneous blood sample.

Many diabetic patients (insulin dependent) are required to self-test for blood glucose levels five to six times daily. The large number of steps required in traditional methods of glucose testing ranging from lancing, to milking of blood, applying blood to the test strip, and getting the measurements from the test strip discourages many diabetic patients from testing their blood glucose levels as often as recommended. Tight control of plasma glucose through frequent testing is therefore mandatory for disease management. The pain associated with each lancing event further discourages patients from testing. Additionally, the wound channel left on the patient by known systems may also be of a size that discourages those who are active with their hands or who are worried about healing of those wound channels from testing their glucose levels.

Another problem frequently encountered by patients who must use lancing equipment to obtain and analyze blood samples is the amount of manual dexterity and hand-eye coordination required to properly operate the lancing and sample testing equipment due to retinopathies and neuropathies particularly, severe in elderly diabetic patients. For those patients, operating existing lancet and sample testing equipment can be a challenge. Once a blood droplet is created, that droplet must then be guided into a receiving channel of a small test strip or the like. If the sample placement on the strip is unsuccessful, repetition of the entire procedure including re-lancing the skin to obtain a new blood droplet is necessary. The manual dexterity and the relatively large number of devices used to sample and then test the blood challenges patients to keep to their testing regimes.

SUMMARY OF THE INVENTION

The present invention provides solutions for at least some of the drawbacks discussed above. Specifically, some embodiments of the present invention provide an improved, integrated fluid sampling device. To improve device integration, devices and methods for connecting sensor regions to contact pad regions may be provided. One of the problems involves getting electrical contact with the leads connected to electrodes

coupled to the sensor regions. At least some of these and other objectives described herein will be met by embodiments of the present invention.

The technical field relates to thick film conductor depositions for the purpose of providing sensory device placement, signal conduction, and isolation from environments detrimental to the sensory device storage and integrity prior to utilization.

A further understanding of the nature and advantages of the invention will become apparent by reference to the remaining portions of the specification and drawings.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides a solution for body fluid sampling. Specifically, some embodiments of the present invention provides a method for improving spontaneous blood generation. The invention may use a high density penetrating member design. It may use penetrating members of smaller size, such as but not limited to diameter or length, than those of conventional penetrating members known in the art. The device may be used for multiple lancing events without having to remove a disposable from the device. The invention may provide improved sensing capabilities. At least some of these and other objectives described herein will be met by embodiments of the present invention.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only and are not restrictive of the invention, as claimed. It may be noted that, as used in the specification and the appended claims, the singular forms "a", "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, reference to "a material" may include mixtures of materials, reference to "a chamber" may include multiple chambers, and the like. References cited herein are hereby incorporated by reference in their entirety, except to the extent that they conflict with teachings explicitly set forth in this specification.

In this specification and in the claims which follow, reference will be made to a number of terms which shall be defined to have the following meanings:

"Optional" or "optionally" means that the subsequently described circumstance may or may not occur, so that the description includes instances where the circumstance occurs and instances where it does not. For example, if a device optionally contains a feature for analyzing a blood sample, this means that the analysis feature may or may not

be present, and, thus, the description includes structures wherein a device possesses the analysis feature and structures wherein the analysis feature is not present.

Figures 1 and 2 provide additional details of the line conductors, feed-throughs, and conductor pads. The embodiment shown in the Figures 1 and 2 may be adapted for use with a radial cartridge such as that shown in commonly assigned, co-pending U.S. Patent Application Ser. No. 10/429,196 (Attorney Docket No. 38187-2662) filed May 1, 2003, fully incorporated herein by reference for all purposes. Figure 7 shows a support structure 12 that is adapted for use with a radial cartridge. The support 12 may include a plurality electrodes such as, but not limited to, a working electrode 40, a counter electrode 42, and a reference electrode 44. A plurality of conduction lines 50 may be used as leads to connect the electrodes having the sensory material 14 with the contact pad 30 on the other side of the support 12 (see Figure 2). The contact pad 30 may be substantially larger in width than the conduction lines 50. This facilitates the tolerance of the pad to slight misalignments of the pad with connectors or contacts on a measurement device. The contact pads 30 are shown to be square or rectangular in geometry. It should be understood, however, that the contact pads 30 may be circular, oval, polygonal, triangular, any single combination of the geometries above, or any combination of any number of the geometries above. The via holes may also be sufficiently spaced apart such that there is sufficient space on the underside of the support structure to accommodate the larger contact pads 30.

The top side of the support 12 may include a sealing region 60. This sealing region 60 may be used to keep the sensor material 14 in a sealed environment prior to use.

Figure 3 shows how one embodiment of a radial cartridge 100 may be coupled to a sterility barrier 102 and a support 12 having the sensor material 14 and contact pads 30. Of course, the support 12 of Figure 3 may be configured to include configuration shown Figures 1 and 2. The support 12 would be sealed, in one embodiment, against the underside of the radial cartridge 100. This integrates the sensory material 14 with the cartridge and also creates the sealed environment in which the material 14 may be stored until ready for use.

This patent takes the sensor electrodes (located anywhere on the bottom on the package) taking advantage of the disc. We can put the sensors anywhere along the disc (between ID and OD). We could put those sensors and use them with a commutator pickup, I could come down with million insertion point probes that are spring loaded into

the door. We could do gold plated sheet metal probes that are bent up. Disc rotates, the next chamber rotates right in line with the contacts.

Referring now to Figure 4, one embodiment of the present invention could use a commutator 200 to engage the electrode leads 202. The commutator 200 may be spring loaded to better engage the leads. As the cartridge rotates as indicated by arrows 204, those lead from electrodes in the active regions come in contact with the commutator 200. Referring back to Figure 2, it can be sent that commutators 200 may be positioned to engage contact pads from the leads; where the pads 30 are not positioned in the inner diameter of the cartridge. The pads 30 may be on the underside, side, or somewhere along the length of the cartridge. It should be understood that a variety of commutators are shown in Figure 4. The device may have one set of commutators or it may have multiple sets. They may all have the same orientation or combinations of orientations. Figure 4 shows side by side, vertical, and spring based versions. These are purely exemplary and nonlimiting.

Referring now to Figure 5, a still further embodiment of the present invention will be described. In one embodiment of the lancing device, the cartridge goes in, foil-side up. If we print on sensors 218 in the chamber, you could have the probes 220 go through the printed material 224, making contact with the sensors. In this embodiment, electrodes at all. In some alternatives, cam action may be used to move the probes out of the way. They go back in, making contact with the next chamber when the cartridge is rotated into place. Thus to get rid of the electrodes, we want to make contact with the printed sensor using a needle probe which may be made by way of example and not limitation, laser etched gold. Alternative embodiments may use laminates. They use various thicknesses of materials. In some embodiments, the probes do not penetrate the sensors in a manner that contacts blood.

While the invention has been described and illustrated with reference to certain particular embodiments thereof, those skilled in the art will appreciate that various adaptations, changes, modifications, substitutions, deletions, or additions of procedures and protocols may be made without departing from the spirit and scope of the invention. For example, with any of the above embodiments, the location of the penetrating member drive device may be varied, relative to the penetrating members or the cartridge. With any of the above embodiments, the penetrating member tips may be uncovered during actuation (i.e. penetrating members do not pierce the penetrating member enclosure or

protective foil during launch). With any of the above embodiments, the penetrating members may be a bare penetrating member during launch. In some embodiments, analyte detecting members may be printed on the top, bottom, or side of the cavities. The front end of the cartridge maybe in contact with a user during lancing. The same driver may be used for advancing and retraction of the penetrating member. The penetrating member may have a diameters and length suitable for obtaining the blood volumes described herein. The penetrating member driver may also be in substantially the same plane as the cartridge. The sensory material 14 may be deposited into the via holes 18. The conductor material may also be deposited into the via holes. The via holes may be formed by a variety of methods including micro drilling, laser drilling, plasma etching, or the like. The embodiments herein are adapted for use with lancing devices described in U.S. Patent Applications Ser. No. 10/127,395 (Attorney Docket No. 38187-2551US) and U.S. Patent Applications Ser. No. 10/323,622 (Attorney Docket No. 38187-2606US). It should understood that any of the inventions herein may be used in conjunction with devices disclosed in U.S. Patent Applications Attorney Docket No. 38187-2551, 38187-2608, and 38187-2662.

The publications discussed or cited herein are provided solely for their disclosure prior to the filing date of the present application. Nothing herein is to be construed as an admission that the present invention is not entitled to antedate such publication by virtue of prior invention. Further, the dates of publication provided may be different from the actual publication dates which may need to be independently confirmed. All publications, patents, and patent applications mentioned herein are incorporated herein by reference to disclose and describe the structures and/or methods in connection with which the publications are cited.

Where a range of values is provided, it is understood that each intervening value, to the tenth of the unit of the lower limit unless the context clearly dictates otherwise, between the upper and lower limit of that range and any other stated or intervening value in that stated range is encompassed within the invention. The upper and lower limits of these smaller ranges may independently be included in the smaller ranges is also encompassed within the invention, subject to any specifically excluded limit in the stated range. Where the stated range includes one or both of the limits, ranges excluding either both of those included limits are also included in the invention.

Expected variations or differences in the results are contemplated in accordance with the objects and practices of the present invention. It is intended, therefore, that the invention be defined by the scope of the claims which follow and that such claims be interpreted as broadly as is reasonable.

WHAT IS CLAIMED IS:

1. A body fluid sampling device comprising:

a support structure;

a sensory material on a first side of said support structure;

a conductor material coupled to the sensory material; and

a commutator positioned to engage said conductor material to obtain analyte measurments.

2. The device of claim 1 further comprising a radial cartridge, said support structure coupled to said radial cartridge.

3. The device of claim 1 further comprising a plurality of electrodes each having said sensory material.

ABSTRACT OF THE DISCLOSURE

A body fluid sampling device is provided. The device comprises a support structure. The device includes sensory material on a substrate and a conductor material in connection with the sensory material. A commutator may be used to engage the conductor material. The commutator may placed in a variety of positions.

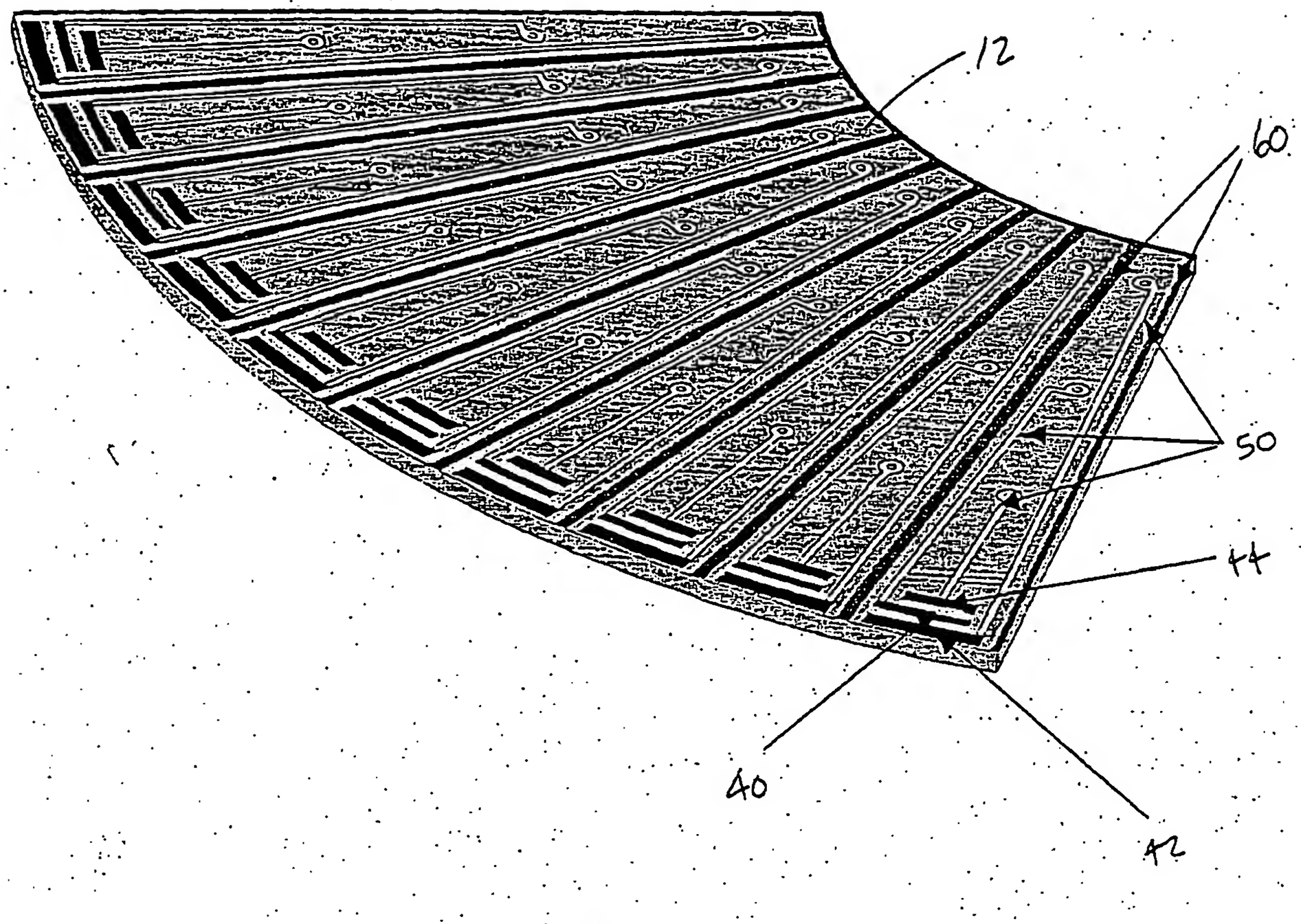
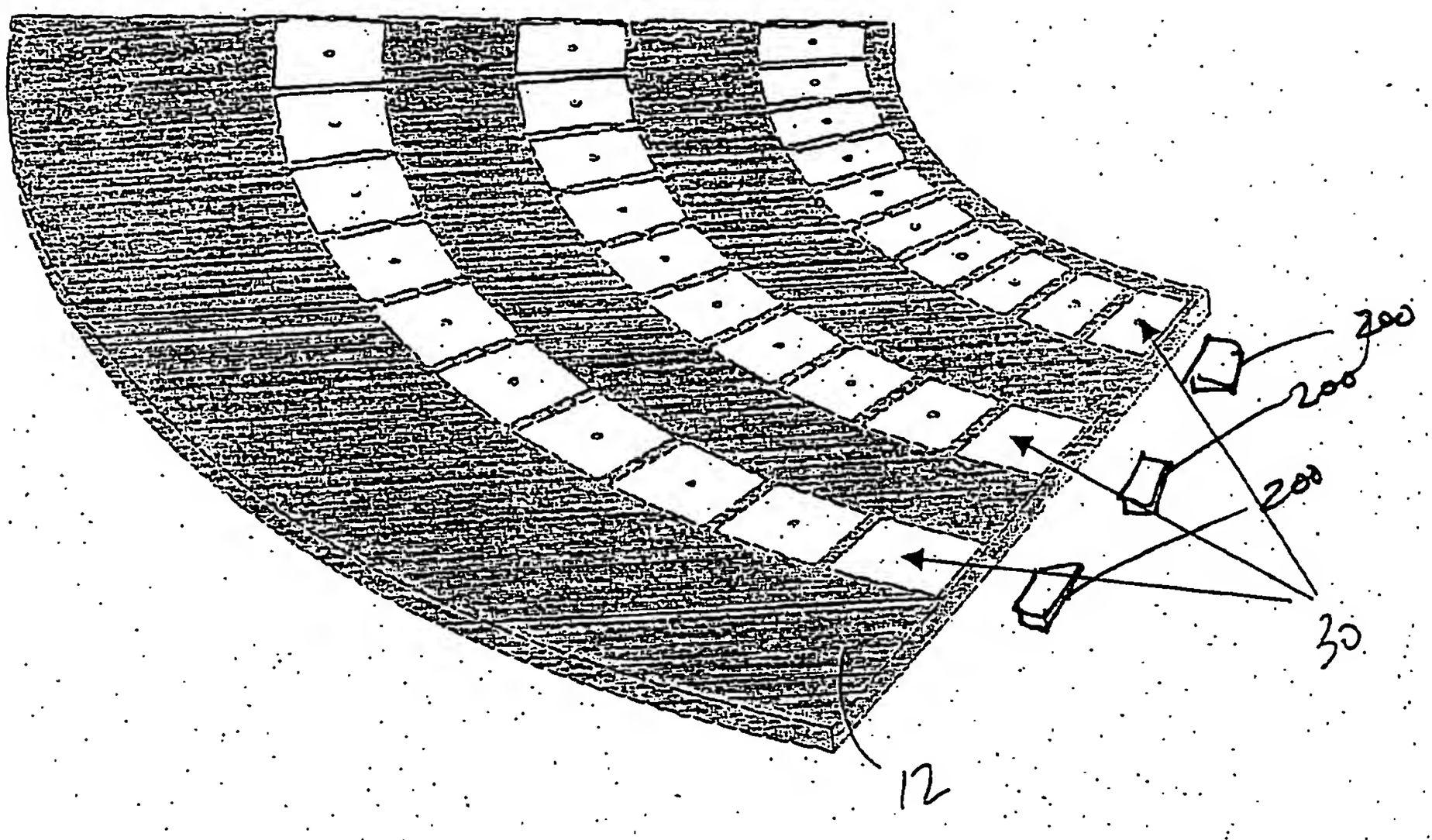


FIG-1



FIG— 2

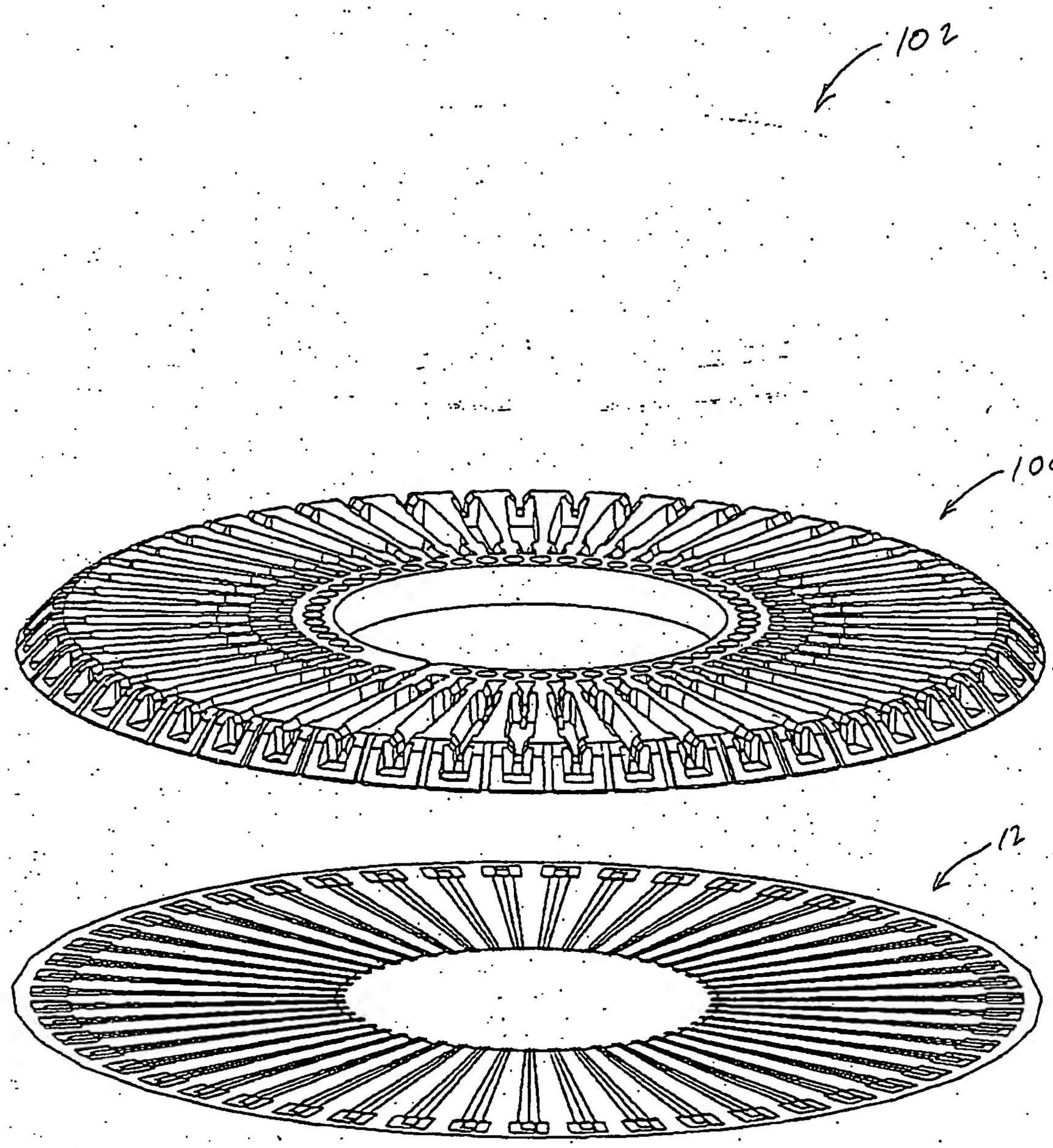


FIG_3

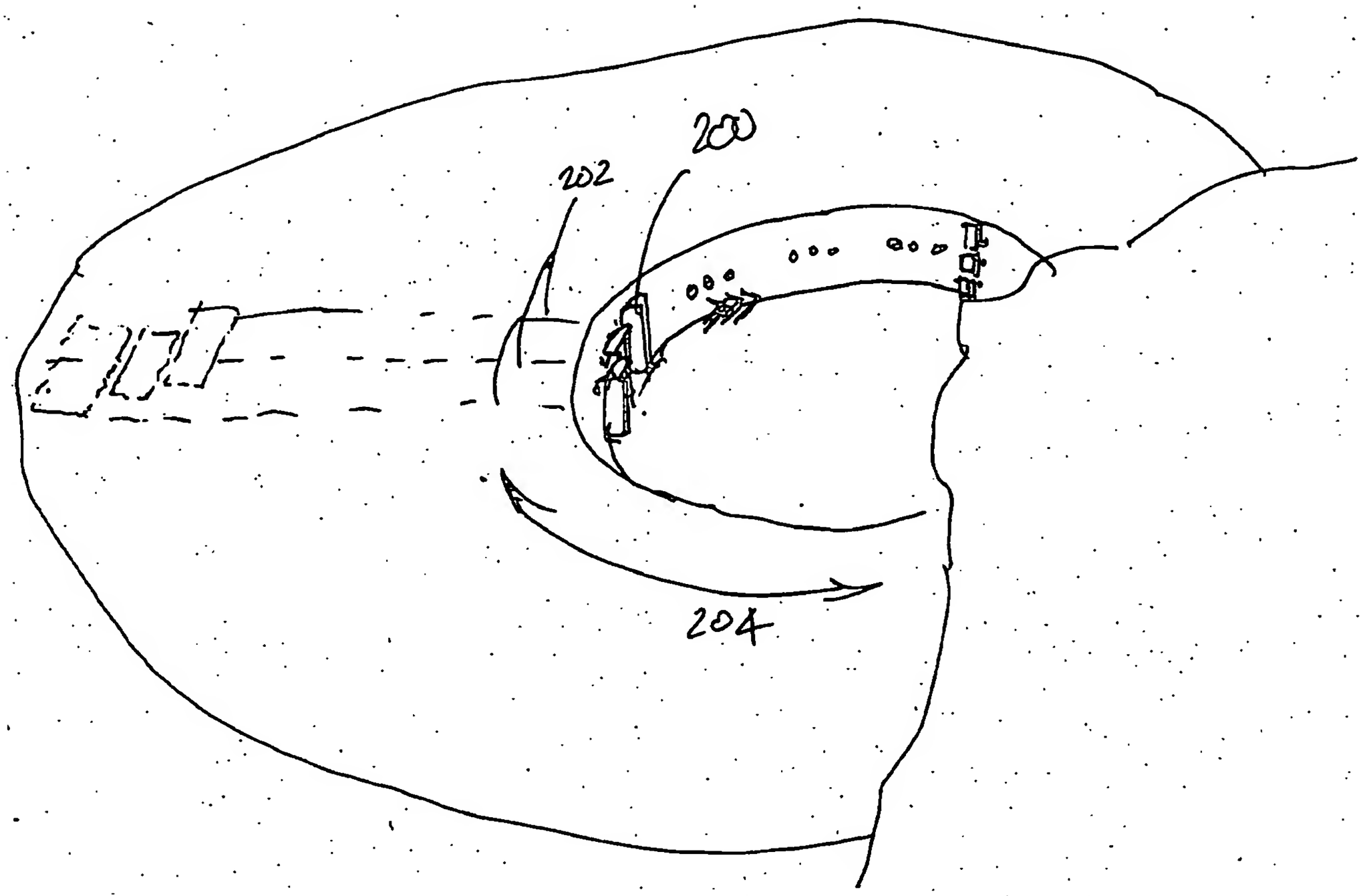


FIG_4

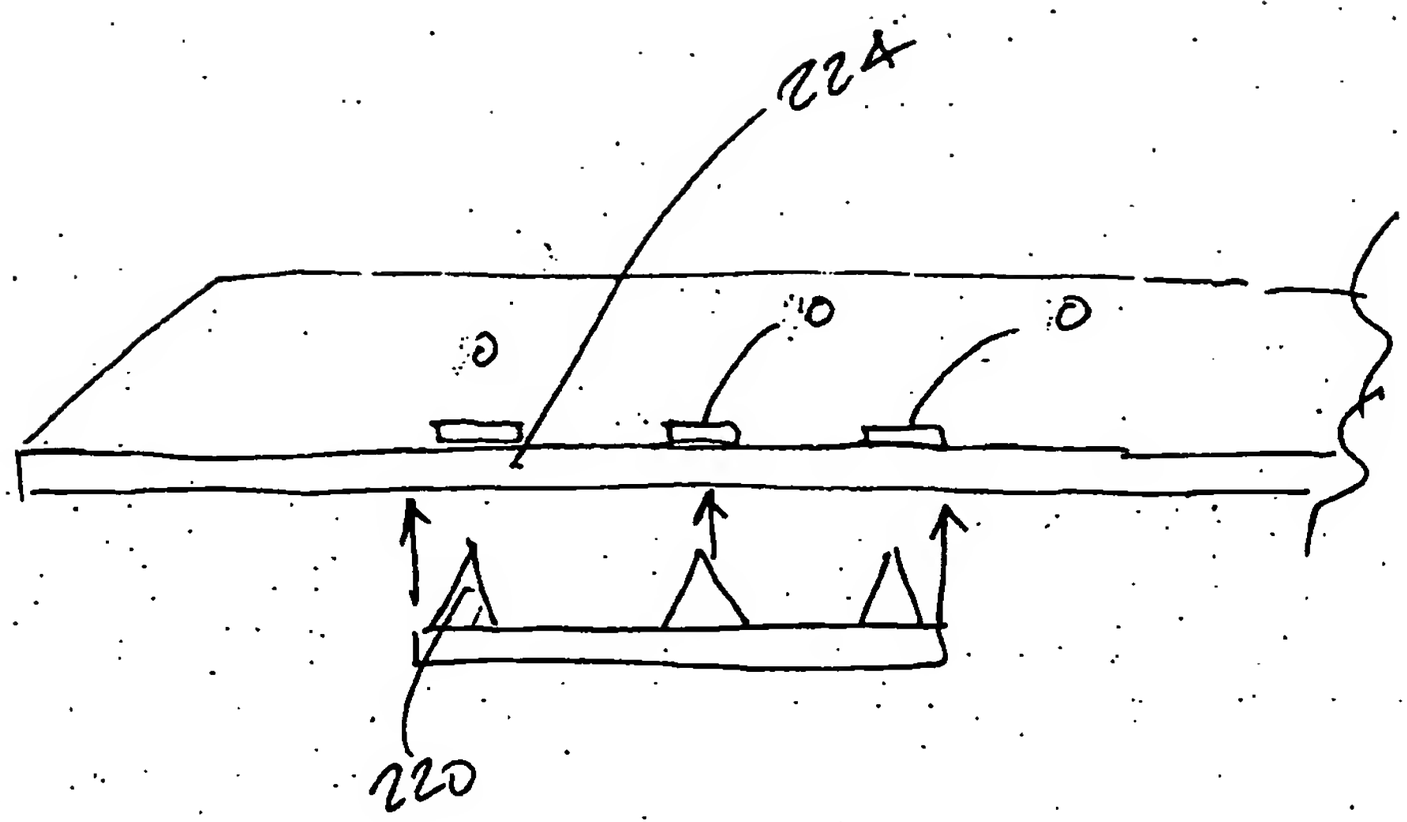


FIG_5

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